

REMARKS

Status of the Claims

Claims 1, 5-30, and 35-68 are pending in this application. Claims 1, 27, 54-56, 61, and 68 are independent. In the final Office Action, claims 9 and 66-68 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In addition, claims 14 and 36-40 were rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite. Also, claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, and 65-68 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith, III (U.S. Patent No. 6,491,928; hereinafter “Smith”). Further, claims 19-26, 28-30, 35, 45, 46, 53, and 58 were rejected under § 103(a) as being unpatentable over Smith in view of Kochinke (U.S. Patent No. 5,350,581; hereinafter “Kochinke”). In addition, claims 43 and 44 were rejected under § 103(a) as being unpatentable over Smith in view of Auguste et al. (U.S. Patent No. 6,338,839; hereinafter “Auguste”). Lastly, claims 12, 13, and 61-64 were rejected under § 103(a) as being unpatentable over Smith in view of Yoko (JP 04108710; hereinafter “Yoko”).

Applicant wishes to thank the Examiner for the withdrawal of the rejection of claims 11, 21-23, and 41 under 35 U.S.C. § 112, second paragraph.

Rejection Under 35 U.S.C. § 112, First Paragraph

With regard to the rejection of claim 9 under 35 U.S.C. § 112, first paragraph, as in the previous Office Action, the pending final Office Action alleges a lack of written description, while the remarks regarding this allegation appear to set forth an argument regarding enablement. For example, the final Office Action repeats the allegation that

[t]he recitation of “freeze-dried substances” without any description of these substances and their correlation to the moisture absorbing compounds does not meet the written description requirement as one of ordinary skill in the art would not recognize or understand . . . what are the freeze dried materials that acts (sic) as moisture absorbing compounds.

Final Office Action at 4. The final Office Action further repeats the allegation that

[t]he expression could encompass myriad of freeze-dried substances and applicants claimed “freeze-dried substances” represents (sic) only an invitation to experiment regarding possible means.

Id.

As explained in MPEP § 2163.04, “a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).” MPEP § 2163.04 further states that “[t]he examiner . . . must have a reasonable basis to challenge the adequacy of the written description” and that “[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Wertheim, 541 F.2d at 263, 191 USPQ at 97.”

Applicant respectfully submits that there is no reasonable basis to challenge the adequacy of the written description and that no further clarification and/or examples are required for one of ordinary skill in the art to understand the scope of the term “freeze-dried substances” in the context of moisture absorbing compounds used in adhesive matrices. The final Office Action asserts that “[n]owhere in the specification [has] applicant . . . disclosed freeze-dried substances that [would be] suitable as moisture

absorbing agents.” Final Office Action at 5. In view of this asserted lack of disclosure of suitable freeze-dried substances by Applicant, the final Office Action concludes that “[o]ne skilled in the art would not recognize the freeze-dried substances that can be used in the present invention as defined by the claims.” Id. However, the Examiner has failed to cite any evidence or provide anything beyond conjecture relating to the issue of what would not have been recognizable to one of ordinary skill in the art. Accordingly, absent any further evidence, the Examiner has not demonstrated by a preponderance of evidence why a person skilled in the art would not recognize the description of the invention defined by the claims. Accordingly, the § 112, first paragraph, rejection should be withdrawn.

With regard to the rejection of claims 66-68 under § 112, first paragraph, Applicant reiterates that recitations in claims 66-68 are supported by the original disclosure, such as, for example, in figures 1-10 and 16. The final Office Action asserts, at page 3, that there is “no disclosure whatsoever in the specification for ‘composite that has substantially constant thickness.’” However, as noted in MPEP § 2163.06, “information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter.” Therefore, since figures 1-10 and 16 clearly show a composite structure having a substantially constant thickness, the recitations in claims 66-68 are properly supported. Accordingly, the rejection of claims 66-68 under § 112, first paragraph, should be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Applicants respectfully traverse the rejection of claims 14 and 36-40 under 35 U.S.C. § 112, second paragraph. As stated in MPEP § 2173.02, “[t]he test for definiteness under 35 U.S.C. § 112, second paragraph, is whether ‘those skilled in the art would understand what is claimed when the claim is read in light of the specification.’” Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).” MPEP § 2173.02 further indicates that a claim is indefinite “[o]nly when a claim remains insolubly ambiguous without discernible meaning after all reasonable attempts at construction.” MPEP § 2173.02 clarifies that, with regard to the requirement of definiteness under 35 U.S.C. § 112, second paragraph, “[t]he essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity.

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.”

In addition, as clearly set forth in MPEP § 2173.04, “[b]readth of a claim is not to be equated with indefiniteness.” MPEP § 2173.04 continues, “[i]f the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. § 112, second paragraph.”

A claim term that is not used or defined in the specification is not indefinite if the meaning of the claim term is discernible. Bancorp Services, L.L.C. v. Hartford Life Ins. Co., 359 F.3d

1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004) (holding that the disputed claim term ‘surrender value protected investment credits’ which was not defined or used in the specification was discernible and hence not indefinite because “the components of the term have well recognized meanings, which allow the reader to infer the meaning of the entire phrase with reasonable confidence”).

MPEP § 2173.02. (Emphasis added).

Claim 14 was rejected because the recitation of “vinyl” allegedly does not “set forth the metes and bounds of the claim.” Office Action at 6. The final Office Action apparently objects to the purported lack of further description and/or examples of applicable vinyl compounds. The final Office Action further alleges that it is ambiguous as to what the term “vinyl” is defined as because, it is purportedly unclear whether the term “vinyl” is intended to define a “chemical vinyl group, monomer, polymer, copolymer, or vinyl compounds, etc.” Final Office Action at 7.

Applicant submits that no further explanation is needed for one of ordinary skill in the art to understand the scope of claim 14. There is no ambiguity as to the meaning and scope of the term “vinyl” in the context of adhesive matrices. Claim 14 specifies that “the adhesive matrix comprises a[n] . . . adhesive comprising one of vinyl, PVA, PVP . . .” (Emphasis added). Applicant respectfully submits that one of ordinary skill in the art would readily understand the scope of “vinyl” as a component of an adhesive matrix. Moreover, the mere fact that Applicant has broadly used the term “vinyl” such that it has not been limited to one of a chemical group, monomer, polymer, copolymer, or compound, does not render the claim indefinite because, as noted above, breadth of a claim is not to be equated with indefiniteness.

Claims 36-40 were rejected under § 112, second paragraph, because the expressions “additional active agent configured to swell,” “additional active agent

soluble in the solvent," and "compound configured to swell," are allegedly not defined in the specification. Office Action at 6. As pointed out in Applicant's previous response, the discussion of an "additional active agent" is found in the specification at, for example, page 14, lines 22-32, which explains that, in some embodiments, the adhesive matrix may include more than one active agent. Applicant respectfully submits that the use of active agents configured to swell in order to facilitate their release from a substrate would be understood by those having ordinary skill in the art. In addition, Applicant respectfully submits that the solubility of the active agent in a solvent is explained sufficiently in the specification, such that no further explanation is necessary to clarify what is meant by "additional active agent soluble in the solvent." See, e.g., page 1, line 25--page 2, line 22.

The final Office Action attempts to point out alleged inconsistencies between the specification and the claims by contrasting the use of the terms "active agents" and "inert compounds." Specifically, the final Office Action cites page 2, lines 17-21 of the specification, alleging that "the specification does not define the active agents such that the adhesive matrix loses cohesion on contact with the solvent, but inert compounds." Final Office Action at 7. However, the specification does not conflict with the claims as alleged, because page 2, lines 5-10 of the specification indicates that, "[i]n a particular embodiment, the adhesive matrix contains one or more active agents . . . in sufficient quantity for the matrix to lose its cohesion on contact with the solvent and to release the active agent(s)." Further, the passage cited by the final Office Action (page 2, lines 17-21) states that "in a particular embodiment, as a variant or in addition, the adhesive matrix contains a filler of one or more substantially inert compounds . . ." Emphasis

added. Therefore, as noted above, the adhesive matrix of the present application, in some embodiments, may include either or both an active agent and/or a filler, each of which contribute to the loss of cohesion of the matrix and consequent release of the active agent/filler. Accordingly, there is no ambiguity in claims 36-40 and, therefore, the rejection of these claims under § 112, second paragraph, should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

The rejection of claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, and 65-68 under § 103(a), based on Smith, fails to establish a prima facie case of obviousness for at least the reason that Smith does not disclose or suggest all the recitations of independent claims 1, 27, 54-56, 61, and 68. For example, Smith fails to disclose a composite structure including, among other things, “at least one adhesive matrix,” as recited in each of independent claims 1, 54-56, 61, and 68. Smith also fails to disclose a method of manufacturing a composite structure including, among other things, “coating a first non-adhesive layer with an adhesive matrix,” as recited in independent claim 27.

The pending final Office Action alleges that Smith discloses a “therapeutic agent comprised within composition comprising adhesive material.” Pending Office Action at 8-9. This allegation is inconsistent with the Office Action mailed May 19, 2004, which admitted that “Smith does not expressly teach that the cleansing composition is in the form of an adhesive matrix.” May 19, 2004 Office Action at 3. Applicant respectfully submits that the May 19, 2004 Office Action was correct in its assessment that Smith does not teach an “adhesive matrix,” as recited in independent claims 1, 27, 54-56, 61, and 68. The portion of Smith cited in the pending final Office Action as allegedly disclosing an adhesive matrix (col. 31, lines 21-25) does not disclose adhesive at all,

but rather a “coacervate forming composition,” which is merely a material tending to form clusters/droplets. Smith lacks any disclosure of the “coacervate forming composition” being an adhesive matrix.

For at least the foregoing reasons, Applicant respectfully submits that Smith fails to disclose or suggest each and every element of the claims. Therefore, at least one essential criteria for establishing a prima facie case of obviousness is lacking and, accordingly, the § 103(a) rejection of claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, and 65 is should be withdrawn.

In addition, the Examiner admits, in the pending Office Action, that Smith fails to teach that “the two non-adhesive substrates are bonded permanently by the middle layer.” Office Action at 9; emphasis added. The Examiner alleges, however, that Smith discloses that “the [alleged] adhesive used by [Smith] in the middle layer comprises acrylic polymer and polyurethane that are claimed by Applicant as permanent adhesive in claim 14 (col. 32, lines 40-43; col. 37, lines [sic] col. 39, lines 16-17).” Office Action at 9. From this alleged disclosure in Smith, the Examiner concludes that “the middle layer disclosed by [Smith] that [allegedly] comprises adhesive including acrylic acid polymer or polyurethane polymers is expected to be able to permanently bond to the first and second non-adhesive substrates[.]” Final Office Action at 9-10. That is, the final Office Action attempts to remedy Smith’s acknowledged failure to disclose an “adhesive matrix” by alleging that components of the purported adhesive material in Smith are claimed by Applicant as permanent adhesive. However, the final Office Action does not point to any suggestion, motivation, or teaching to modify the alleged adhesive in Smith into a permanent adhesive. Moreover, contrary to the allegations in

the final Office Action, the present application does NOT disclose that the materials in claim 14 (i.e., acrylic polymer and polyurethane) are necessarily permanent adhesives. Rather, the present application discloses a permanent adhesive which can include acrylic polymer and polyurethane as possible components of the permanent adhesive.

Acrylic and polyurethane are broad categories of polymers, which include many different materials that have many varied uses. Adhesive materials are only one of many known forms of such materials. Accordingly, the simple fact that Smith might mention acrylic and polyurethane does not provide any suggestion, motivation, or teaching to modify these materials to be a permanent adhesive. Therefore, another essential criteria for establishing a prima facie case of obviousness is lacking. For at least the foregoing reasons, the § 103(a) rejection of claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, and 65-68 should be withdrawn.

In addition, with regard to claims 66-68, the final Office Action alleges that Smith "does not teach that the thickness of the article changes, therefore, it is constant." Office Action at 10. However, figure 3 of Smith clearly shows the cross section of the disclosed article having tapered thickness toward both ends.

It is noteworthy that the final Office Action purportedly finds no description in the present application or Smith about the thickness of the respectively disclosed articles, yet reaches opposite conclusions about what the respective disclosures teach. Specifically, in the portions dealing with the claims rejection under 35 U.S.C. §112, first paragraph, the final Office Action effectively finds that absent a verbatim description in the present specification, there is purportedly no support for the claim recitations of a substantially constant thickness, but with regard to Smith, concludes that absent any

teaching in Smith that the thickness varies, it must be constant. Therefore, another essential criteria for establishing a *prima facie* case of obviousness is lacking.

For at least the foregoing reasons, the § 103(a) rejection of claims 1, 5-11, 14-18, 27, 36-42, 47-52, 54-57, 59, 60, and 65-68 should be withdrawn.

With regard to the § 103(a) rejection of claims 19-26, 28-30, 35, 45, 46, 53, and 58 as being unpatentable over Smith in view of Kochinke, the final Office Action acknowledges that Smith “does not teach more than one superimposed layers [sic] containing adhesive or pile of the article[.]” Office Action at 11. In an attempt to cure this acknowledged deficiency of Smith, the Office Action relies on Kochinke solely for an alleged disclosure of a multilayer device having “more than one therapeutic agent contained in different adhesive matrices.” Id. However, Kochinke does not cure the deficiencies of Smith noted above with regard to independent claims 1, 27, and 56, from which claims 19-26, 28-30, 35, 45, 46, 53, and 58 respectively depend. For at least this reason, the § 103(a) rejection of claims 19-26, 28-30, 35, 45, 46, 53, and 58 should be withdrawn.

With regard to the § 103(a) rejection of claims 43 and 44 as being unpatentable over Smith in view of Auguste, the final Office Action acknowledges that Smith “does not teach the polyamide in the powder form.” Final Office Action at 13. The final Office Action relies on Auguste for the sole purpose of attempting to cure this acknowledged deficiency of Smith. However, Auguste does not cure the above-noted deficiencies of Smith with regard to independent claim 1, from which claims 43 and 44 ultimately depend. For at least this reason, the § 103(a) rejection of claims 43 and 44 should be withdrawn.

With regard to the § 103(a) rejection of claims 12, 13, and 61-64 as being unpatentable over Smith in view of Yoko, the final Office Action acknowledges that Smith “does not teach magnetizable particles in the therapeutic composition.” Final Office Action at 15. The Office Action relies on Yoko for the sole purpose of attempting to cure this acknowledged deficiency of Smith. However, Yoko does not cure the above-noted deficiencies of Smith with regard to independent claim 1, from which claims 12 and 13 ultimately depend, nor does it cure the deficiencies of Smith with regard to independent claim 61, which recites at least one “adhesive matrix.” For at least these reasons, the § 103(a) rejection of claims 12, 13, and 61-64 should be withdrawn.

Conclusion

For at least the foregoing reasons, Applicant respectfully submits that each of independent claims 1, 27, 54-56, 61, and 68 is allowable. Each of claims 5-26, 30, 35-53, 57-60, and 62-67 ultimately depends from one of these allowable independent claims and, therefore, should be allowable for at least the same reasons that the respective claim from which it depends is allowable. Additionally, these dependent claims include further limitations that distinguish from the cited art.

The Office Action contains a number of statements reflecting assertions and/or allegations concerning the claims and/or cited art. Regardless of whether any such statement is identified above, Applicant declines to subscribe to any assertion or allegation in the Office Action.

In view of the above, Applicant respectfully requests that the rejections be withdrawn and that the application be allowed. Please grant any additional extensions of time required to enter this response and charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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